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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/171,909

05/09/2001

Jayanta Roy-Chowdhury

ENZ-55(CIP)PC

8638

21967

7590

06/20/2005

EXAMINER

SCHWADRON, RONALD B

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INTELLECTUAL PROPERTY DEPARTMENT
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SUITE 1200
WASHINGTON, DC 20006-1109

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/171,909

Applicant(s)

ROY-CHOWDHURY ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. Applicant's election with traverse of Group I in the reply filed on 4/5/2005 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Regarding applicants comments, 37 CFR 1.499 states:

Unity of invention during the national stage

If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under § 1.143 and 1.144.

The claimed inventions lack unity of invention for the reasons elaborated in the previous Office Action. The determinations in the ISR are irrelevant because the claimed inventions lack unity of invention for the reasons elaborated in the previous Office Action. Regarding applicants comments, **original claims 90 and 91 in parent application 08/808629 indicate that the selective immune suppressive can be a cytokine or anti T cell antibody such as anti-CD4.** The original claims of said application indicate that the selective immunosuppressive can be anti-CD4 antibody. Wilson et al. disclose use of anti-CD4 antibody and/or cytokines as selected immune modulators wherein the administered agents inhibit the formation of neutralizing antibodies and/or reduce CTL against said virally infected cells. Applicant has also not addressed the prior art cited in the ISR. The claimed inventions also lack unity of invention in view of the prior art rejection cited in this Office action.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 4-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/5/2005.

3. Regarding references not considered on the enclosed PTO-1449, 09/447704 is not a parent application of the instant application. Therefore, cited references were not considered wherein a copy of said reference was not supplied.

4. Applicant needs to amend the first line of page 1 of the specification to indicate that the instant application is a 371 of PCT US98/03606 which is a CIP of 08/808629 filed 2/28/97 (now abandoned).

5. The term "selective immune down regulation" is interpreted as per its definition in the specification, page 8, first paragraph.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (WO 96/39176) in view of Katz (US Patent 4,950,469).

Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen (see claims 1-13, pages 12-14,40,41). Oral tolerance is a

form of "selective immune down regulation" (see specification, page 17, second paragraph). Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever. Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues (see specification, page 17, second paragraph). Katz teaches that agents which prevent binding of said antibodies could be used to treat rheumatic fever (see specification, page 17, second paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen whilst Katz teaches that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues wherein the streptococcal antigens would function as an autoantigen. One of ordinary skill in the art would have been motivated to do the aforementioned because Chen et al. teach use of oral tolerance to prevent antibody responses causing autoimmune diseases and Katz disclose that anti streptococcal antibodies are involved in rheumatic fever and that neutralization of said antibodies could be used to treat said disease.


8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644


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PRIMARY EXAMINER
GROUP 1800-1644